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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,846	10/23/2001	Darryl Y. Sasaki		5512

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EXAMINER

LAVILLA, MICHAEL E

ART UNIT	PAPER NUMBER
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1775

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/041,846	Applicant(s) SASAKI ET AL.	
	Examiner Michael La Villa	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20011023</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to a self-assembled lipid bilayer material, classified in class 428, subclass 220.
 - II. Claims 12-17, drawn to a method of making a lipid bilayer material, classified in class 427, subclass 213.3.
 - III. Claim 18, drawn to a method of making a specific lipid bilayer material, classified in class 264, subclass 4.3.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions of Group I and of Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a lipid bilayer material not having a columnar structure, but rather a single-layered structure.
4. Inventions of Group I and of Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a process that involves a different copper ion source.

5. Inventions of Group II and of Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve processes that both result in lipid bilayer materials. However, the materials of Group III are necessarily columnar and of specific composition, formed by a sequence of steps, which steps are not recited among the steps of Group II. Hence, the inventions are not related.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
7. Because these inventions are distinct for the reasons given above and the search required for any of Groups I-III is not required for any of the others of Groups I-III, restriction for examination purposes as indicated is proper.
8. During a telephone conversation with Mr. Klavatter on 1 June 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

10. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).
11. At least at page, line 20 and page 7, line 13, and possibly elsewhere, applicant has incorporated by reference materials that are other than United States patent applications or patents. Where applicant has incorporated by reference essential material, this is improper and hereby objected to.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

13. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- I. Regarding Claim 1, it is unclear what is meant by the phrase "columnar structure with self-limiting radial dimension". Particularly, it is unclear how "self-limiting" is further defining of the phrase "self-assembled". Applicant's method of making these materials involves forming liposomes that are then broken down due to recognition chemistry to form the plurality of bilayers in a column. The self-limited diameter may be a consequence of the initial liposome diameter, rather than any intrinsic self-limiting quality of the assembly interactions. Is this what is referred to by the phrase "self-limiting"? Does this entire phrase necessarily imply a certain orientation of the plurality of bilayer molecules in the columnar structure that is claimed? It is also unclear what is meant by the phrase "mediated by chemical recognition events". Any molecular structure that forms is mediated by "chemical recognition events". Hence, it is unclear what is the required structure or composition in order to ascertain whether a material was obtained with the claimed "chemical recognition events".
- II. Regarding Claim 2, it is unclear whether the claimed diameters pertain only to one particular lipid bilayer molecule of the plurality of lipid

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bilayer molecules, to all of the plurality of lipid bilayer molecules each having its own diameter which must obtain at least one of the claimed values, or to each of the plurality of lipid bilayer molecules having the same diameter, said diameter being one in the claimed range.

- III. Regarding Claim 5, it is unclear what is the relationship, if any, of the claimed "mediated by chemical recognition events" of Claim 1 to the "ligand promoting adhesion".
- IV. Regarding Claim 9, it is unclear what is the relationship, if any, of the claimed "mediated by chemical recognition events" of Claim 1 to the "functionalized with a receptor molecule".
- V. Regarding Claims 7 and 8, it is unclear what is the antecedent basis of the phrase "said ligand."
- VI. Regarding Claim 10, it is unclear what is the antecedent basis of the phrase "said receptor."

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- 16. A person shall be entitled to a patent unless –
- 17. (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 18. (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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19. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1, 3, 4, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenk et al. USP 5,925,375. Lenk et al. teaches multilamellar liposomes comprised of a plurality of lipid bilayers. Each such liposome resting on a surface may be deemed to constitute a columnar structure. See Lenk et al. (col. 6, line 63 through col. 7, line 49; col. 8, lines 19-40; col. 9, lines 43-60; col. 15, line 50 through col. 18, line 49).

21. Claims 1, 3-7, 9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Safniya et al. USP 6,358,523. Safniya et al. teaches stacked lipid bilayer materials that are sandwiching DNA molecules. See Safniya et al. (Figures 3, 5, 10; col. 2, lines 26-55; col. 8, lines 29-42; col. 17, lines 6-44; col. 20, line 9 through col. 22, line 10; col. 25, line 50 through col. 32, line 5).

22. Claims 1-7, 9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Firestone et al. USP 6,537,575. Firestone et al. teaches self-assembled columnar lipid bilayer materials as claimed. The diameters, since the spacing is exemplified as 357 angstroms, would approximate 900 angstroms depending on the definition of diameter. The length would appear to be in excess of the claimed 300 angstroms in view of the photomicrographs, which depict the relative size of the diameter and length. Firestone teaches including incorporating proteins and other moieties as claimed in Claim 11, and the disclosed graft polymer of Firestone may be identified with the materials of Claim 11. See

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Firestone et al. (Figures 1-5; col. 4, line 65 through col. 5, line 52; col. 6, line 48 through col. 8, line 30).

23. Claims 1-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Waggoner et al. in "Self-Assembled Columns of Stacked Lipid . . . " in JACS 123 (3) 496-7 (2001). Waggoner et al. teaches the claimed self-assembled lipid bilayer materials. See Waggoner et al. (entire document). Applicant has characterized this reference as being publicly available prior to applicant's filing date and as exemplifying the claimed invention. See Specification at page 7, line 13. The authorship of Waggoner et al. is different from the inventorship of this patent application, and so publication "by others" is presumed absent evidence to the contrary.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael La Villa whose telephone number is (571) 272-1539. The examiner can normally be reached on Monday through Friday.
25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on (571) 272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael La Villa
June 15, 2004

A handwritten signature in black ink, appearing to read "La Villa", with a long horizontal flourish extending to the right.